

MAY 24 2004 IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Steven K. Burke

Application No.: 10/686,808 Group Art Unit: 1646

Filed: October 16, 2003 Examiner: Not Yet Assigned

Confirmation No.: 8791

Title: METHOD FOR PROMOTING BONE FORMATION

CERTIFICATE OF MAILING OR TRANSMISSION

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Rachel Meehan  
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RACHEL MEEHAN

Typed or printed name of person signing certificate

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)

under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

under 37 CFR 1.97(c) together with either:

a Statement under 37 CFR 1.97(e), as checked below, or

a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

under 37 CFR 1.97(d) together with:

a Statement under 37 CFR 1.97(e), as checked below, and

a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- [ ] Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- [ ] No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- [ ] Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

[X] Enclosed herewith is form PTO-1449:

[X] Copies of the cited references are enclosed.

[X] Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.

[ ] Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]

[X] The listed references (AL, AM & AR-AT) were cited in the enclosed International Search Report in a counterpart foreign application.

[ ] The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:

[ ] the explanation provided on the attached sheet.

[ ] the explanation provided in the Specification.

[ ] submission of the enclosed International Search Report.

[ ] submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.

[ ] the enclosed English language abstract.



[ ] Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

- \_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]  
 \_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]  
 \_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_ Examiner

\_\_\_\_ Date

- [ ] A copy of each above-cited application, including the current claims, is enclosed.  
 [ ] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- [ ] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.  
 [ ] Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.  
 [X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Jesse A. Fecker  
 Jesse A. Fecker  
 Registration No.: 52,883  
 Telephone: (978) 341-0036  
 Facsimile: (978) 341-0136

Concord, MA 01742-9133

Dated: 5-20-04

PTO-1449 REPRODUCED

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INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION  
MAY 24 2004  
May 11, 2004  
(Use several sheets if necessary)

ATTORNEY DOCKET NO.  
1932.2135-002APPLICATION NO.  
10/686,808FIRST NAMED INVENTOR  
Steven K. BurkeFILING DATE  
October 16, 2003EXAMINER  
Not Yet AssignedCONFIRMATION NO.  
8791GROUP  
1646

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AA	US 2002/0051822 A1	05-02-2002	Atherton <i>et al.</i>
	AB	5,487,888	01-30-1996	Mandeville, III <i>et al.</i>
	AC	5,496,545	03-05-1996	Holmes-Farley <i>et al.</i>
	AD	5,607,669	03-04-1997	Mandeville, III <i>et al.</i>
	AE	5,618,530	04-08-1997	Mandeville, III <i>et al.</i>
	AF	5,624,963	04-29-1997	Mandeville, III <i>et al.</i>
	AG	5,667,775	09-16-1997	Mandeville, III <i>et al.</i>
	AH	5,679,717	09-16-1997	Holmes-Farley <i>et al.</i>
	AI	5,703,188	12-30-1997	Mandeville, III <i>et al.</i>
	AJ	5,702,696	12-30-1997	Mandeville, III <i>et al.</i>
	AK	5,693,675	12-02-1997	Mandeville, III <i>et al.</i>
	AA2	5,900,475	05-04-1999	Mandeville, III <i>et al.</i>
	AB2	5,925,379	07-20-1999	Mandeville, III <i>et al.</i>
	AC2	6,083,497	07-04-2000	Huval <i>et al.</i>
	AD2	6,177,478	01-23-2001	Holmes-Farley <i>et al.</i>
	AE2	6,083,495	07-04-2000	Holmes-Farley <i>et al.</i>
	AF2	6,203,785	03-20-2001	Holmes-Farley <i>et al.</i>
	AG2	6,423,754	07-23-2002	Holmes-Farley <i>et al.</i>
	AH2	6,509,013	01-21-2003	Holmes-Farley <i>et al.</i>
	AI2	6,556,407	04-29-2003	Brando <i>et al.</i>
	AJ2	US 2002/0159968 A1	10-31-2002	Petersen <i>et al.</i>
	AK2	US 2003/0086898 A1	05-08-2003	Holmes-Farley <i>et al.</i>
	AA3	US 2003/0133902 A1	07-17-2003	Holmes-Farley <i>et al.</i>
	AB3	6,726,905	04-27-2004	Mandeville, III <i>et al.</i>
	AC3	6,733,780	05-11-2004	Tyler <i>et al.</i>
	AD3	US 2002/0182168 A1	12-05-2002	Holmes-Farley <i>et al.</i>

EXAMINER

DATE CONSIDERED

PTO-1449 REPRODUCED			ATTORNEY DOCKET NO. 1932.2135-002	APPLICATION NO. 10/686,808	
INFORMATION DISCLOSURE CITATION IN AN APPLICATION			FIRST NAMED INVENTOR Steven K. Burke	FILING DATE October 16, 2003	
May 11, 2004  (Use several sheets if necessary)			EXAMINER Not Yet Assigned	CONFIRMATION NO. 8791	GROUP 1646

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EXAMINER INITIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AE3	6,566,407	05-20-2003	Holmes-Farley <i>et al.</i>
	AF3	US 2002/0187120 A1	12-12-2002	Holmes-Farley <i>et al.</i>
	AG3	US 2002/0168333 A1	11-14-2002	Burke
	AH3	US 2002/0187121 A1	12-12-2002	Burke
	AI3	US 2003/0049226 A1	03-13-2003	Burke <i>et al.</i>
	AJ3	US 2003/0039627 A1	02-27-2003	Holmes-Farley <i>et al.</i>

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES      NO
	AL	WO 03/057225 A2	07-17-2003	Genzyme Corporation	
	AM	WO 93/04373	03-04-1993	NPS Pharmaceuticals, Inc.	

OTHER DOCUMENTS (*Including Author, Title, Date, Pertinent Pages, Etc.*)

AR	Moe, S., <i>et al.</i> , "Sevelamer HCL Improves Parathyroid Hormone (PTH) and Bone Function in Peritoneal Dialysis (PD) Patients With Probable Low Turnover Bone Disease," <i>American J. of Kidney Diseases</i> , 37(4): A25 (abstract only-Tenth Annual Clinical Nephrology Meeting Abstracts), (2001).
AS	Raggi, P., <i>et al.</i> , "Sevelamer Preserves and Calcium Reduces Trabecular Bone Mineral Density," <i>J. American Society of Nephrology</i> , 14: 502A (abstract only), (2003).
AT	Katsumata, K., <i>et al.</i> , "Sevelamer Hydrochloride Prevents Ectopic Calcification and Renal Osteodystrophy in Chronic Renal Failure Rats," <i>Kidney International</i> , 64: 441-450 (2003).
AU	Slatopolsky, E.A., <i>et al.</i> , "RenaGel®, a Nonabsorbed Calcium- and Aluminum-Free Phosphate Binder, Lowers Serum Phosphorus and Parathyroid Hormone," <i>Kidney International</i> , 55: 299-307 (1999).

EXAMINER	DATE CONSIDERED
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PTO-1449 REPRODUCED  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  May 11, 2004  (Use several sheets if necessary)		ATTORNEY DOCKET NO. 1932.2135-002	APPLICATION NO. 10/686,808
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			GROUP 1646

<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
AV	Chertow, G.M., <i>et al.</i> , "Sevelamer With and Without Calcium and Vitamin D: Observations From a Long-Term Open-Label Clinical Trial," <i>J. Of Renal Nutrition</i> , 10(3): 125-132 (2000).		
AW	Chertow, G.M., <i>et al.</i> , "Hyperparathyroidism and Dialysis Vintage," <i>Clinical Nephrology</i> , 54(4): 295-300 (2000).		
AX	Malluche, H.H., and Mawad, H., "Management of Hyperphosphataemia of Chronic Kidney Disease: Lessons From the Past and Future Directions," <i>Nephrol. Dial. Transplant.</i> , 17: 1170-1175 (2002).		
AY	Cannata-Andía, J.B., and Rodríguez-García, M., "Hyperphosphataemia as a Cardiovascular Risk Factor - How to Manage the Problem," <i>Nephrol. Dial. Transplant.</i> , 17(Suppl. 11): 16-19 (2002).		
AZ	Nolan, C.R., and Qunibi, W.Y., "Calcium Salts in the Treatment of Hyperphosphatemia in Hemodialysis Patients," <i>Current Opinion in Nephrology and Hypertension</i> , 12: 373-379 (2003).		
AR2	Čižman, B., "Hyperphosphataemia and Treatment With Sevelamer in Haemodialysis Patients," <i>Nephrol. Dial. Transplant.</i> , 18(Suppl. 5): v47-v49 (2003).		
AS2	Coco, M., and Rush, H., "Increased Incidence of Hip Fractures in Dialysis Patients With Low Serum Parathyroid Hormone," <i>Am. J. Kidney Diseases</i> , 36(6): 1115-1121 (2000).		
AT2	Taal, M.W., <i>et al.</i> , "Risk Factors for Reduced Bone Density in Haemodialysis Patients," <i>Nephrol. Dial. Transplant.</i> , 14: 1922-1928 (1999).		
AU2	Taal, M.W., <i>et al.</i> , "Total Hip Bone Mass Predicts Survival in Chronic Hemodialysis Patients," <i>Kidney International</i> , 63: 1116-1120 (2003).		
AV2	Braun, J., <i>et al.</i> , "Electron Beam Computed Tomography in the Evaluation of Cardiac Calcifications in Chronic Dialysis Patients," <i>American J. Kidney Diseases</i> , 27(3): 394-401 (1996).		
AW2	Cozzolino, M., <i>et al.</i> , "Role of Calcium-Phosphate and Bone-Associated Proteins on Vascular Calcification in Renal Failure," <i>J. Am. Soc. Nephrol.</i> , 12: 2511-2516 (2001).		
AX2	Loghman-Adham, M., "Phosphate Binders for Control of Phosphate Retention in Chronic Renal Failure," <i>Pediatr. Nephrol.</i> , 13: 701-708 (1999).		
AY2	Elder, G., "Pathophysiology and Recent Advances in the Management of Renal Osteodystrophy," <i>J. Bone and Mineral Research</i> , 17(12): 2094-2105 (2002).		

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			GROUP 1646

<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
AZ2	Bardin, T., "Musculoskeletal Manifestations of Chronic Renal Failure," <i>Curr. Opin. Rheumatol.</i> , 15: 48-54 (2003).		
AR3	Albaaj, F., and Hutchison, A.J., "Hyperphosphataemia in Renal Failure (Causes, Consequences and Current Management)," <i>Drugs</i> , 63(6): 577-596 (2003).		
AS3	Martin, C.J., and Reams, S.M., "The Renal Dietitian's Role in Managing Hyperphosphatemia and Secondary Hyperparathyroidism in Dialysis Patients: A National Survey," <i>J. Renal Nutrition</i> , 13(2): 133-136 (2003).		
AT3	Fontaine, M.A., <i>et al.</i> , "Fracture and Bone Mineral Density in Hemodialysis Patients," <i>Clinical Nephrol.</i> , 54(3): 218-226 (2000).		
AU3	Kleinpeter, M.A., "Spectrum of Complications Related to Secondary Hyperparathyroidism in a Peritoneal Dialysis Patient," <i>Advances in Peritoneal Dialysis</i> , 16: 286-290 (2000).		
AV3	Chertow, G.M., <i>et al.</i> , "Poly(allylamine hydrochloride) (RenaGel®): a noncalcemic phosphate binder for the treatment of hyperphosphatemia in chronic renal failure," <i>Am. J. Kid. Dis.</i> , 29: 66-71 (1997).		
AW3	Goldberg, D.I., <i>et al.</i> , "Effect of RenaGel, a non-absorbed, calcium-and aluminum-free phosphate binder, on serum phosphorus, calcium, and intact parathyroid hormone in end-stage renal disease patients," <i>Nephrol. Dial. Transplant.</i> , 13: 2303-2310 (1998).		
AX3	Chertow, G.M., <i>et al.</i> , "A randomized trial of sevelamer hydrochloride (RenaGel®) with and without supplemental calcium. Strategies for the control of hyperphosphatemia in hemodialysis patients," <i>Clin. Nephrol.</i> , 51: 18-26 (1999).		
AY3	Bleyer, A.J., <i>et al.</i> , "A comparison of the calcium-free phosphate binder sevelamer hydrochloride with calcium acetate in the treatment of hyperphosphatemia in hemodialysis patients," <i>Am. J. Kid. Dis.</i> , 33: 694-701 (1999).		
AZ3	Chertow, G.M., <i>et al.</i> , "Long-term effects of sevelamer hydrochloride on the calcium x phosphorus product and lipid profile of haemodialysis patients," <i>Nephrol. Dial. Transplant.</i> , 14: 2907-2914 (1999).		
AR4	Chertow, G.M., <i>et al.</i> , "Sevelamer attenuates the progression of coronary and aortic calcification in hemodialysis patients," <i>Kidney Int.</i> , 62: 245-252 (2002).		

EXAMINER	DATE CONSIDERED
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